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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,377	02/26/2002	Catherine Defrenne	BM45379	4141

25308 7590 09/08/2004

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/936,377	DEFRENNE ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *see attached*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☒ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *NONE*.

   Claim(s) objected to: *32*.

   Claim(s) rejected: *25,27,29,31,35,40,41,43 and 47-51*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

The newly added claims 52-56 recite the limitation "recombinant" that has not been searched earlier in the prosecution and would require further search and consideration.

Applicant's request for reconsideration of art rejections under 35 U.S.C. 112 first paragraph is considered but does not place the application in condition for allowance because of the following reasons:

Applicant's arguments for claims 25, 27, 29, 31, 35, 40, 41, 43 and 47-51 did not overcome the rejection under 35U.S.C.112, first paragraph because the claimed immunogenic peptides are not limited to SEQ.ID.NO: 2. The specification fails to teach the claimed immunogenic peptides because an isolated polypeptide comprising (open language) a member selected from the group consisting of an immunogenic fragment comprising at least 15 contiguous amino acids plus unlimited and unknown amino acids of SEQ.ID.NO: 2 would result in unknown peptides without sufficient structure and completely lacking identifying characteristics such as function. Thus, fragments as claimed are broader than SEQ.ID.NO: 2. Further, inducing an immune response is not an identifying characteristic (function) of a fragment because there are many fragments with the same function in a polypeptide and such variants are not distinguishable from each other. Therefore claims 25, 27, 29, 31, 35, 40, 41, 43 and 47-51 fail to overcome the rejection under 35U.S.C.112, first paragraph and enablement.

The examiner has reviewed, Geysen et al., Pros. Natl. Acad. Sci. USA 1984, 81, 3998-4002 (exhibit D in Applicant's amendment of 4/19/04) Reece et al., J. of Immunology 1993, 6175-6184 exhibit A (which was attached as exhibit A in Applicant's amendment of 4/19/04) and Current Protocols in Immunology 1997 9.7.1-9.7.19 and Reece et al., 172 J. of Immunol. 1994 241 (previously attached as Exhibit C).

With respect to Exhibit D, Applicant states that the Office action's contention is that the claims are not enabled for mixture of peptides.

The examiner has never stated or indicated that the claims are not enabled for a mixture of peptides and it was neither the examiner's nor the office action's contention that the claims are not enabled for mixture of fragments of SEQ.ID.NO; 2. The immunogenic fragments as claimed i.e., immunogenic fragment comprising at least 15 contiguous amino acids plus unlimited and unknown amino acids of SEQ.ID.NO: 2 are not enabled as explained previously in the office action.

With respect to Exhibit A, B, and C, Applicant states that Reece et al., the difficulties of protein processing were overcome by synthesizing overlapping dodecapeptides on pins to map T-cell epitopes of tetanus toxin. Pools of 20 peptides each were used to simplify the mapping assays. Thus, it was practical to synthesize a large number of peptides, and the initial screen needed only to assay sixty to seventy pools. Pools of 20 peptides each were used to simplify the mapping assays.

The examiner disagrees with the applicant because Reece et al clearly identified the problem of using long peptides or partially fragmented antigen could fail to reveal immunodominant regions of the antigen and therfore used a set of 1304 overlapping 12mer peptides spanning the 1315 residues of the sequence. However, applicant is not claiming overlapping 15 mer peptides of SEQ.ID.NO: 2 but claiming polypeptide larger than SEQ.ID.NO:2, i.e., an immunogenic polypeptide comprising at least 15 contiguous amino acids of SEQ.ID.NO: 2 . Thus the claimed fragments are not limited to short overlapping dodecapeptides as taught by Reece et al. Therefore, an immunogenic fragment comprising at least 15 contiguous amino acids plus unlimited and unknown amino acids of SEQ.ID.NO: 2 (long peptides) would fail to reveal the reveal immunodominant regions of the antigen as stated by Reece et al . Further, the claimed immunogenic fragments have not been shown to stimulate/or expand T-cells specific for a Neisserial antigen (SEQ.ID.NO: 2) and is left for experimentation as discussed in the previous office action.